

addressed to the Secretary of Commerce, Attention: Import Administration, Central Records Unit, Room B-099, Department of Commerce, Pennsylvania Avenue at 14th St., NW., Washington, D.C., 20230, and, if hand-delivered, between the hours of 8:30 a.m. and 5:00 p.m. on Government business days.

(2) *Form and number of copies.* Unless the Secretary determines in advance of the submission that the requirements of this paragraph are unjust or unduly burdensome, any submission intended to be considered in connection with a proceeding shall be subject to the following requirements. Documents shall be submitted in 10 copies, public and non-public versions considered as separate documents. They shall be submitted on letter-size paper, double-spaced, not permanently bound, but held securely together by a single staple, fastener, binder clip or other form of clamp. They shall be marked in the upper right hand corner of the cover or top page with the following information in the following format: On the first line, except for petitions, the ITA case number; on the second line, the total number of pages of the submission including cover pages, appendices, and other unnumbered pages; beginning on the third line, a statement indicating whether the document contains or does not contain privileged, confidential, or business proprietary information, or information subject to administrative protective order. Include the page numbers where any such information is located. Individual pages containing such information shall also be marked, in accordance with section 353.28. Unless date-stamped by the Central Records Unit and submitted in conformity with this paragraph, the Secretary may refuse to accept such information or written views for consideration in the administrative record.

(3) *Copies for parties to the proceeding.* A copy shall also be served at the same time, by mail or personal service, on counsel for each party to the proceeding as of the date of the filing. If the party is not represented by counsel, the person designated for this purpose by the party to the proceeding shall be served. A certificate of service shall accompany each filing. The Secretary shall effect the service if he or she determines that it will be unduly burdensome on the party to the proceeding.

(5 U.S.C. 301, 15 U.S.C. 1512, 1513, 44 FR 69273, Sections 2(a) and 5(a)(1)(C) and (F))

Dated: May 18, 1984.

Alan F. Holmer,
Deputy Assistant Secretary for Import
Administration.

[FR Doc. 84-14031 Filed 5-29-84; 8:45 am]

BILLING CODE 3510-DS-M

19 CFR Part 355

[Docket No. 40313-28A]

Countervailing Duties

AGENCY: International Trade Administration.

ACTION: Final rule.

SUMMARY: 19 CFR Part 355 specifies requirements for submitting information and written views in countervailing duty investigations conducted by the International Trade Administration. This final rule will change the site and certain filing requirements thereby streamlining the Administration's operational efficiency and public records maintenance.

EFFECTIVE DATE: May 30, 1984.

FOR FURTHER INFORMATION CONTACT: John L. Evans, Deputy to the Deputy Assistant Secretary for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Ave., NW., Washington, D.C., 20230, Room 3099B (202) 377-1780.

SUPPLEMENTARY INFORMATION: Since this rule relates to agency practice and procedures requirements, it is exempt from the notice and comment procedures described in section 553 of the Administrative Procedures Act (5 U.S.C. 553). It is also exempt from the requirements of the Regulatory Flexibility Act (15 U.S.C. 701, *et seq.*). As a non-substantive rule, publication may be less than 30 days before it is effective. This rule is not a major rule as defined in section 1(b) of Executive Order 12291 (46 FR 13193, February 19, 1981), "Federal Regulation" because it will (1) have no major monetary effect on the economy, (2) result in no major increase in costs or prices, and (3) have no significant adverse effects on competition (domestic or foreign), employment, investment, productivity or innovation.

This rule does not contain a collection of information for purposes of the Paperwork Reduction Act of 1980.

This regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

List of Subjects in 19 CFR Part 355

Countervailing duties.

PART 355—[AMENDED]

Accordingly, 19 CFR Part 355 is amended as follows:

§ 355.26 [Amended]

1. Section 355.26(a) is amended by replacing the words "Secretary, attention: assistant Secretary for Trade Administration, Room 3850, Department of Commerce, Washington, D.C. 20230" with "Secretary of Commerce, Attention: Import Administration, Central Records Unit, Room B-099, Department of Commerce, Pennsylvania Avenue at 14th Street, NW., Washington, D.C. 20230."

2. Section 355.34(a) is revised to read as follows:

§ 355.34 Submission of information and written views.

(a) Submission of information and written views.

(1) *When and where to file.* Except in situations where it would be manifestly unjust, any information or written views submitted in connection with a proceeding shall be considered only if received within the time established by these regulations or by specific instructions applicable to such submission; any submission received after such time shall not be considered in the proceeding. Documents shall be addressed to the Secretary of Commerce, Attention: Import Administration, Central Records Unit, Room B-099, Department of Commerce, Pennsylvania Avenue at 14th St., NW., Washington, D.C. 20230, and, if hand-delivered, between the hours of 8:30 a.m. and 5:00 p.m. on Government business days.

(2) *Form and number of copies.* Unless the Secretary determines in advance of the submission that the requirements of this paragraph are unjust or unduly burdensome, any submission intended to be considered in connection with a proceeding shall be subject to the following requirements. Documents shall be submitted in 10 copies, public and non-public versions considered as separate documents. They shall be submitted on letter-size paper, double-spaced, not permanently bound, but held securely together by a single staple, fastener, binder clip or other form of clamp. They shall be marked in the upper right hand corner of the cover or top page with the following information in the following format: on the first line, except for petitions, the ITA case number; on the second line, the total

number of pages of the submission including cover pages, appendices, and other unnumbered pages; beginning on the third line, a statement indicating whether the document contains or does not contain privileged, confidential, or business proprietary information, or information subject to administrative protective order. Include the page numbers where any such information is located. Individual pages containing such information shall also be marked, in accordance with section 355.18. Unless date-stamped by the Central Records Unit and submitted in conformity with this paragraph, the secretary may refuse to accept such information or written views for consideration in the administrative record.

(3) *Copies for parties to the proceeding.* A copy shall also be served at the same time, by mail or personal service, on counsel for each party to the proceeding as of the date of the filing. If the party is not represented by counsel, the person designated for this purpose by the party to the proceeding shall be served. A certificate of service shall accompany each filing. The Secretary shall effect the service if he or she determines that it will be unduly burdensome on the party to the proceeding.

Authority: 5 U.S.C. 301, 15 U.S.C. 1512, 1513, 44 FR 69273, sections 2(a) and 5(a)(1) (C) and (F).

Dated: May 18, 1984.

Alan F. Holmer,
Deputy Assistant Secretary for Import
Administration.

[FR Doc. 84-14030 Filed 5-29-84; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 82F-0308]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame in chewable multivitamin food supplements. This action responds to a petition filed by the Rexall Corp.

DATES: Effective May 30, 1984; objection by June 29, 1984.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of October 15, 1982 (47 FR 46140), FDA announced that a petition (FAP 2A3662) had been filed by the Rexall Corp., 3901 North Kingshighway Blvd., St. Louis, MO 63115, proposing that the food additive regulations be amended to provide for the safe use of aspartame (1-methyl *N*-L- α -aspartyl-L-phenylalanine) as a sweetener in multivitamin food supplements.

FDA, having evaluated the data in the petition and other relevant material, concludes that this proposed food additive use is safe and that it represents a minor increase in the level of exposure to aspartame for dry uses. (See Aspartame; Commissioner's Final Decision, 46 FR 38285; July 24, 1981.) FDA based this decision on data indicating that the exposure from the use in chewable multivitamins is considerably less than the exposure from uses already approved by the agency. Aspartame consumption resulting from a daily dose of chewable multivitamins would add approximately 10 mg per person to the daily diet. In the 2- to 4-year-old group, this intake would add approximately 1 milligram per kilogram (mg/kg) or less to the 90th percentile estimated daily intake of 24 mg/kg resulting from all other foods, including carbonated beverages, containing aspartame. Chewable multivitamins would contribute less than 2 percent to the total acceptable daily intake of 50 mg/kg. Thus, the approval of the use of aspartame to sweeten chewable multivitamins contributes a relatively minor increase in the individual's potential daily intake of the sweetener, and does not significantly affect current estimates of daily intake. Therefore, the regulation should be amended as set forth below.

FDA recently approved the use of aspartame as a sweetener in carbonated beverages (48 FR 31376; July 8, 1983). The preamble to that final rule contains additional discussion of the safety of aspartame. Two objections and requests for a stay and a hearing were filed in response to the carbonated beverage

regulation. FDA concluded that a stay of the carbonated beverage regulation was unwarranted (48 FR 52899; November 23, 1983), and subsequently denied the request for a hearing (49 FR 6672; February 22, 1984). In denying the request for a hearing, the agency concluded that aspartame is safe at the levels of exposure that would result from its incorporation into carbonated beverages. (See 49 FR at 6677-6679.)

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives; Food preservatives; Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 172 is amended in § 172.804 by adding new paragraph (c)(7) to read as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

§ 172.804 Aspartame.

...

(c) ...

(7) Chewable multivitamin food supplements.

...

Any person who is adversely affected by the foregoing regulation may at any time on or before June 29, 1984 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be

separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective May 30, 1984.

(Secs. 210(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: May 17, 1984.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 84-14367 Filed 5-29-84; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 83F-0264]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

Correction

In FR Doc. 84-11772 beginning on page 18735 in the issue of Wednesday, May 2, 1984, make the following correction:

On page 18736, first column, in the table, under the entry "Substances", fourth line, "B" should have read "β".

BILLING CODE 1505-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Iodinated Casein Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to codify a previously approved new animal drug application (NADA) sponsored by Agri-

Tech, Inc. The NADA provides for the use of iodinated casein tablets for use in dogs for decreased thyroid activity manifested by skin and hair coat conditions.

EFFECTIVE DATE: May 30, 1984.

FOR FURTHER INFORMATION CONTACT: Bob Griffith, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112, is the sponsor of NADA 13-502 which provides for use of Protamone-D (iodinated casein) in dogs. The drug is labeled for use in cases of apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy. The drug was approved by letter dated April 22, 1966.

Approvals at the time were not codified by publication in the *Federal Register*. This action codifies the previously approved NADA but does not change the approved use of the drug. Because the application was approved before July 1, 1975, the sponsor is not required to submit a summary of the safety and effectiveness data and information under the freedom of information provisions of the animal drug regulations in 21 CFR

514.11(e)(2)(ii). However, a summary of the basis for approval is available upon request in accordance with 21 CFR 514.11(e)(2)(i).

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drug, Oral use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), Part 520 is amended by adding new § 520.1157 to read as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 520.1157 Iodinated casein tablets.

(a) *Specifications.* Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor.* See No. 017762 in

§ 510.600(c) of this chapter.

(c) *Conditions of use.*—(1) *Amount.* ½ to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use.* For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, seborrhea, thickening of the skin, hyperpigmentation, and lethargy.

(3) *Limitations.* If no response is observed in 30 to 45 days, the drug should be withdrawn and the diagnosis reconsidered. Do not use in the presence of cardiac disease, ischemia, adrenal insufficiency, or nephrosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. May 30, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: May 23, 1984.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 84-14370 Filed 5-29-84; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-176; Reference Notice No. 466]

Altus Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: This final rule establishes a viticultural area in Arkansas to be known as "Altus." The Bureau of Alcohol, Tobacco and Firearms believes that the establishment of the Altus viticultural area and the subsequent use of its name in wine labeling and advertising will enable industry to label wines more precisely, and will help consumers to better identify the wines from this area.

EFFECTIVE DATE: June 29, 1984.

FOR FURTHER INFORMATION CONTACT: Steve Simon, FAA, Wine and Beer